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                                                               HOUSE FILE 722
                                          AN ACT
   4 PROVIDING FOR THE ESTABLISHMENT OF AN INFORMATION
          PROGRAM FOR DRUG PRESCRIBING AND DISPENSING
   6
          PROVIDING PENALTIES, AND PROVIDING AN EFFECTIVE
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      BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF IOWA:
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  Section 1. Section 22.7, Code Supplement 2005, is amended 12 by adding the following new subsection:
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          NEW SUBSECTION. 52. The information contained in the
1 14 information program established in section 124.510A, except to
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      the extent that disclosure is authorized pursuant to section
1 16 124.510C.
          Sec. 2.
                      NEW SECTION.
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                                       124.510A INFORMATION PROGRAM FOR
1 18 DRUG PRESCRIBING AND DISPENSING.
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          Contingent upon the receipt of funds pursuant to section
1 20 124.510G sufficient to carry out the purposes of this
1 21 division, the board, in conjunction with the advisory council
  22 created in section 124.510E, shall establish and maintain an 23 information program for drug prescribing and dispensing. The
1 24 program shall collect from pharmacies dispensing information
  25 for controlled substances identified pursuant to section 26 124.510D, subsection 1, paragraph "g". The information 27 collected shall be used by prescribing practitioners and
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  28 pharmacists on a need=to=know basis for purposes of improving
1 29 patient health care by facilitating early identification of 1 30 patients who may be at risk for addiction, or who may be
1 31 using, abusing, or diverting drugs for unlawful or otherwise
  32 unauthorized purposes at risk to themselves and others, or who 33 may be appropriately using controlled substances lawfully
  34 prescribed for them but unknown to the practitioner. For
  35 purposes of this division, "prescribing practitioner" means a
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    1 practitioner who has prescribed or is contemplating the
   2 authorization of a prescription for the patient about whom
    3 information is requested, and "pharmacist" means a practicing
   4 pharmacist who is actively engaged in and responsible for the 5 pharmaceutical care of the patient about whom information is
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    6 requested. The board shall collect, store, and disseminate
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   7 program information consistent with security criteria 8 established by rule, including use of appropriate encryption
   9 or other industry=recognized security technology. The board
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  10 shall seek any federal waiver necessary to implement the
  11 provisions of the program.
          Sec. 3. <u>NEW SECTION</u>. 124.510B INFORMATION REPORTING.
1. Each licensed pharmacy that dispenses controlled
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2 14 substances identified pursuant to section 124.510D, subsection 2 15 1, paragraph "g", to patients in the state, and each licensed 2 16 pharmacy located in the state that dispenses such controlled
  17 substances identified pursuant to section 124.510D, subsection
2 18 1, paragraph "g", to patients inside or outside the state,
2 19 unless specifically excepted in this section or by rule, shall
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  20 submit the following prescription information to the program:
          a. Pharmacy identification.b. Patient identification.
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          c. Prescriber identification.
              The date the prescription was issued by the prescriber. The date the prescription was dispensed.
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          d.
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          e.
          f.
              An indication of whether the prescription dispensed is
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  27 new or a refill.
               Identification of the drug dispensed.
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          g.
               Quantity of the drug dispensed.
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              The number of days' supply of the drug dispensed.
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               Serial or prescription number assigned by the pharmacy. Type of payment for the prescription.
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          j.
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          1.
               Other information identified by the board and advisory
  34 council by rule.
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               Information shall be submitted electronically in a
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   1 secure format specified by the board unless the board has
    2 granted a waiver and approved an alternate secure format.
               Information shall be timely transmitted as designated
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4 by the board and advisory council by rule, unless the board 5 grants an extension. The board may grant an extension if 6 either of the following occurs:

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The pharmacy suffers a mechanical or electronic а. 8 failure, or cannot meet the deadline established by the board for other reasons beyond the pharmacy's control.

b.

- The board is unable to receive electronic submissions. This section shall not apply to a prescriber 3 12 furnishing, dispensing, supplying, or administering drugs to 3 13 the prescriber's patient, or to dispensing by a licensed 3 14 pharmacy for the purposes of inpatient hospital care, 3 15 inpatient hospice care, or long=term residential facility 3 16 patient care.
- Sec. 4. <u>NEW SECTION</u>. 124.510C INFORMATION ACCESS. 1. The board may provide information from the program to 3 19 the following:
- a. (1) A pharmacist or prescriber who requests the 21 information and certifies in a form specified by the board 3 22 that it is for the purpose of providing medical or 23 pharmaceutical care to a patient of the pharmacist or 24 prescriber. Neither a pharmacist nor a prescriber may 3 25 delegate program information access to another individual.
- (2) Notwithstanding subparagraph (1), a prescriber may 27 delegate program information access to another licensed health 3 28 care professional only in emergency situations where the 3 29 patient would be placed in greater jeopardy if the prescriber 3 30 was required to access the information personally.
- b. An individual who requests the individual's own program 3 32 information in accordance with the procedure established in 3 33 rules of the board and advisory council adopted under section 34 124.510D.
 - c. Pursuant to an order, subpoena, or other means of legal compulsion for access to or release of program information 2 that is issued based upon a determination of probable cause in the course of a specific investigation of a specific 4 individual.
 - 2. The board shall maintain a record of each person that 6 requests information from the program. Pursuant to rules adopted by the board and advisory council under section 8 124.510D, the board may use the records to document and report 9 statistical information.
- 4 10 Information contained in the program and any 4 11 information obtained from it, and information contained in the 4 12 records of requests for information from the program, is 4 13 privileged and strictly confidential information. Such 4 14 information is not a public record pursuant to chapter 22, and 4 15 is not subject to discovery, subpoena, or other means of legal 16 compulsion for release except as provided in this division. 4 17 Information from the program shall not be released, shared 4 18 with an agency or institution, or made public except as 4 19 provided in this division.
- Information collected for the program shall be retained in the program for four years from the date of dispensing. 4 21 4 22 The information shall then be destroyed.
- 5. A pharmacist or other dispenser making a report to the 4 24 program reasonably and in good faith pursuant to this division 4 25 is immune from any liability, civil, criminal, or 4 26 administrative, which might otherwise be incurred or imposed 4 27 as a result of the report.
- 4 28 6. Nothing in this section shall require a pharmacist or 29 prescriber to obtain information about a patient from the 30 program. A pharmacist or prescriber does not have a duty and 4 31 shall not be held liable in damages to any person in any civil 32 or derivative criminal or administrative action for injury, 33 death, or loss to person or property on the basis that the 34 pharmacist or prescriber did or did not seek or obtain or use 35 information from the program. A pharmacist or prescriber 1 acting reasonably and in good faith is immune from any civil, criminal, or administrative liability that might otherwise be 3 incurred or imposed for requesting or receiving or using 4 information from the program.
 - The board shall not charge a fee to a pharmacy, 6 pharmacist, or prescriber for the establishment, maintenance, or administration of the program, including costs for forms 8 required to submit information to or access information from 9 the program, except that the board may charge a fee to an 10 individual who requests the individual's own program 11 information. A fee charged pursuant to this subsection shall 12 not exceed the actual cost of providing the requested 13 information and shall be considered a repayment receipt as 14 defined in section 8.2.

5 15 NEW SECTION. 124.510D RULES AND REPORTING. Sec. 5. 1. The board and advisory council shall jointly adopt 5 17 rules in accordance with chapter 17A to carry out the purposes 5 18 of, and to enforce the provisions of, this division. 5 19 rules shall include but not be limited to the development of 5 20 procedures relating to:

a. Identifying each patient about whom information is 5 22 entered into the program.

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b. An electronic format for the submission of information 5 24 from pharmacies.

5 25 c. A waiver to submit information in another format for a 5 26 pharmacy unable to submit information electronically.

d. An application by a pharmacy for an extension of time 28 for transmitting information to the program.

The submission by an authorized requestor of a request 5 30 for information and a procedure for the verification of the 5 31 identity of the requestor.

5 32 f. Use by the board or advisory council of the program 5 33 request records required by section 124.510C, subsection 2, to 34 document and report statistical information.

g. Including all Schedule II controlled substances and those substances in Schedules III and IV that the advisory 2 council and board determine can be addictive or fatal if not 3 taken under the proper care and direction of a prescriber.

Access by a pharmacist or prescriber to information in the program pursuant to a written agreement with the board and 6 advisory council.

The correction or deletion of erroneous information in i. the program.

2. Beginning January 1, 2007, and annually by January 1 10 thereafter, the board and advisory council shall present to 11 the general assembly and the governor a report prepared 6 11 6 12 consistent with section 124.510E, subsection 3, paragraph "d", 6 13 which shall include but not be limited to the following: 6 14 a. The cost to the state of implementing and maintaining

6 15 the program.

b. Information from pharmacies, prescribers, the board, 6 17 the advisory council, and others regarding the benefits or 6 18 detriments of the program.

c. Information from pharmacies, prescribers, the board, 6 20 the advisory council, and others regarding the board's 6 21 effectiveness in providing information from the program. 6 22 Sec. 6. <u>NEW SECTION</u>. 124.510E ADVISORY COUNCIL Sec. 6. <u>NEW SECTION</u>. 6 23 ESTABLISHED.

An advisory council shall be established to provide 6 25 oversight to the board and the program and to comanage program 6 26 activities. The board and advisory council shall jointly 27 adopt rules specifying the duties and activities of the 6 28 advisory council and related matters.

1. The council shall consist of eight members appointed by 30 the governor. The members shall include three licensed 31 pharmacists, four physicians licensed under chapter 148, 32 or 150A, and one licensed prescriber who is not a physician. 33 The governor shall solicit recommendations for council members 34 from Iowa health professional licensing boards, associations, 6 35 and societies. The license of each member appointed to and 1 serving on the advisory council shall be current and in good 2 standing with the professional's licensing board.

The council shall advance the goals of the program, 4 which include identification of misuse and diversion of 5 controlled substances identified pursuant to section 124.510D, subsection 1, paragraph "g", and enhancement of the quality of health care delivery in this state.

3. Duties of the council shall include but not be limited to the following:

Ensuring the confidentiality of the patient, 7 11 prescriber, and dispensing pharmacist and pharmacy.

12 b. Respecting and preserving the integrity of the 13 patient's treatment relationship with the patient's health 7 14 care providers.

c. Encouraging and facilitating cooperative efforts among 7 16 health care practitioners and other interested and 7 17 knowledgeable persons in developing best practices for 7 18 prescribing and dispensing controlled substances and in 19 educating health care practitioners and patients regarding 7 20 controlled substance use and abuse.

Making recommendations regarding the continued benefits 22 of maintaining the program in relationship to cost and other 23 burdens to the patient, prescriber, pharmacist, and the board. 24 The council's recommendations shall be included in reports $7\ 25\ \text{required}$ by section 124.510D, subsection 2.

One physician and one pharmacist member of the council 7 27 shall include in their duties the responsibility for 28 monitoring and ensuring that patient confidentiality, best 7 29 interests, and civil liberties are at all times protected and 7 30 preserved during the existence of the program. 4. Members of the advisory council shall be eligible to 32 request and receive actual expenses for their duties as 33 members of the advisory council, subject to reimbursement 34 limits imposed by the department of administrative services, 7 35 and shall also be eligible to receive a per diem compensation as provided in section 7E.6, subsection 1.
Sec. 7. NEW SECTION. 124.510F EDUCATION AND TREATMENT. 8 8 8 The program for drug prescribing and dispensing shall 4 include education initiatives and outreach to consumers, 5 prescribers, and pharmacists, and shall also include 8 8 6 assistance for identifying substance abuse treatment programs 8 The board and advisory council shall adopt 7 and providers. 8 8 rules, as provided under section 124.510D, to implement this 8 9 section. 8 1.0 Sec. 8. NEW SECTION. 124.510G DRUG INFORMATION PROGRAM 8 11 FUND. 8 12 The drug information program fund is established to be used 8 13 by the board to fund or assist in funding the program. The 8 14 board may make deposits into the fund from any source, public 8 15 or private, including grants or contributions of money or 8 16 other items of value, which it determines necessary to carry 8 17 out the purposes of this division. Moneys received by the 8 18 board to establish and maintain the program must be used for 8 19 the expenses of administering this division. Notwithstanding 8 20 section 8.33, amounts contained in the fund that remain 21 unencumbered or unobligated at the close of the fiscal year 8 22 shall not revert but shall remain available for expenditure 8 23 for the purposes designated in future years. 8 2.4 Sec. 9. <u>NEW SECTION</u>. 124.510H PROHIBITED ACTS == 8 25 PENALTIES. 1. FAILURE TO COMPLY WITH REQUIREMENTS. A pharmacist, 8 26 8 27 pharmacy, or prescriber who knowingly fails to comply with the 28 confidentiality requirements of this division or who delegates 8 29 program information access to another individual is subject to 8 30 disciplinary action by the appropriate professional licensing 31 board. A pharmacist or pharmacy that knowingly fails to 32 comply with other requirements of this division is subject to 8 8 33 disciplinary action by the board. Each licensing board may 8 34 adopt rules in accordance with chapter 17A to implement the 8 35 provisions of this section. 2. UNLAWFUL ACCESS, DISCLOSURE, OR USE OF INFORMATION. 9 2 person who intentionally or knowingly accesses, uses, or 9 3 discloses program information in violation of this division, 4 unless otherwise authorized by law, is guilty of a class "D" 9 5 felony. This section shall not preclude a pharmacist or 6 prescriber who requests and receives information from the 7 program consistent with the requirements of this chapter from 9 9 8 otherwise lawfully providing that information to any other 9 9 person for medical or pharmaceutical care purposes. 9 10 Sec. 10. Sections 124.510A through 124.510H are repealed 11 June 30, 2009. 12 Sec. 11. EFFECTIVE DATE. This Act, being deemed of 9 12 9 13 immediate importance, takes effect upon enactment. 9 14 9 15 9 16 9 CHRISTOPHER C. RANTS 17 18 Speaker of the House 9 19 20 9 2.1 9 22 JEFFREY M. LAMBERTI 9 23 President of the Senate 9 2.4 I hereby certify that this bill originated in the House and 9 26 is known as House File 722, Eighty=first General Assembly. 2.7 28 9 29 9 30 MARGARET THOMSON Chief Clerk of the House 31 _____, 2006 32 Approved _ 33 9 34

1 THOMAS J. VILSACK